

# Marc Dann Declaration in Support of Motion for Class Certification

## Exhibit 6

**Charles Livingston Werntz III, D.O., MPH, FACOEM, FAOCOPM**

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**EDUCATION**

**West Virginia University**, Morgantown, West Virginia

Masters of Public Health – May 2002

Concentration in Occupational and Environmental Health

**Kirksville College of Osteopathic Medicine**, Kirksville, Missouri.

Doctor of Osteopathic Medicine - June, 1996

Honors: Student Leadership Award Scholarship 1992-93

Student Ambassador Award 1996

**Temple University**, Philadelphia, Pennsylvania

January 1990 to May 1991. Pre-medical science courses.

**Montgomery County Community College**, Blue Bell, Pennsylvania

1987 to 1989. German courses for personal enrichment.

**Drexel University**, Philadelphia, Pennsylvania

B.S., Commerce and Engineering - June 1987

Fields of Concentration - Operations and Human Resources Management

Honors: Deans List 1985-86.

**POST  
GRADUATE  
TRAINING**

**West Virginia University**, Morgantown, West Virginia. July 2000 to June 2002

Residency in Occupational Medicine

Honors: ACOEM Residents Research Presentation Award

Chief Resident July 1, 2001 – December 31, 2001

**West Virginia University**, Morgantown, West Virginia. June, 1997 to June, 2000.

Residency in Internal Medicine, Primary Care Track.

Honors: Department of Medicine Community Service Award 1999

**Community General Osteopathic Hospital**, Harrisburg, PA. July 1996 to June 1997

Traditional rotating internship with weekly half-day ambulatory care experience.

**EMPLOYMENT**

**Morgantown Occupational Medicine, PLLC**, Morgantown, WV

July, 2018 – Present. Principal, Physician, and Consultant.

- Occupational Medicine consulting, focusing on community exposures, medical monitoring programs, occupational injuries, and diseases
- Regulatory Exams (Senior Aviation Medical Examiner, Commercial Drivers, Medical Review Officer, Respirator Examinations)
- Independent Medical Evaluations (4th, 5th, and 6th editions of AMA Guides)
- Occupational surveillance program design and implementation
- Federal Black Lung Examinations at Preston Memorial Hospital
- Morgantown Clinic at Pro Medical Rehabilitation

**Cabin Creek Health Systems**, Dawes, WV

July 2018 – Present - Physician (Part time) – performing Department of Labor Black Lung exams.

**National Institutes for Occupational Safety and Health**, Morgantown, WV

November 2002-Present (Part time). Intermittent Consultant in Surveillance Branch of the Division of Respiratory Health, Coal Worker Health Surveillance Program. Contacting miners with abnormal x-ray finding, and providing physician support for the spirometry monitoring program.

**West Virginia University / West Virginia University Medical Corporation**

August 2002 to February 2003. Clinical Instructor

December 1, 2019

Curriculum Vitae of Charles L. Werntz III, D.O., MPH

December 1, 2019

Page 2 of 7

March 2003 to June 2009. Assistant Professor (Clinical Emphasis).

July 2009 – June 2018. Associate Professor (Clinical Emphasis)

- Program Director ACGME Occupational Medicine Residency (2012-2015)
- Clinical care for injured/exposed workers
- Independent Medical Evaluations (4<sup>th</sup>, 5<sup>th</sup>, and 6<sup>th</sup> editions of AMA Guides)
- Medical support of WVU animal handler & Biosafety health programs
- Medical Review Officer (MROCC)
- FAA Senior Aviation Medical Examiner, FAA Employee Examiner
- Surveillance exams for federal and state agencies
- Program Director – AOA Occupational Medicine Residency 2008-11
- On-site fitness for duty and wellness exams
- DOL Black Lung Examiner (413b)
- Formal Teaching (WVU – for-credit classes):
  - Medical Toxicology for Occupational Medicine Residents
  - Occupational Health Class
  - Small Group Facilitator – MS 1 Clinical Skills Course
  - Global Public Health
- University Biosafety Committee – voting member
- Consultant on health effects of workplace & environmental exposures

**Louis A Johnson VA Medical Center**, Clarksburg, WV

October 2000 to January 2003. Fee-Basis Medical-Officer-of-the-Day. Provide outpatient urgent care and hospital inpatient coverage 1-2 shifts each month.

**MG Industries Gas Products**

April 1991 to August 1992. Production Scheduler. – Fairless Hills, PA

Coordinated production schedules, programmed on-site RF data system for a computerized manufacturing management system. Member of company HazMat response team (Specialist in Gases & Cryogenics).

January 1990 to April 1991. Second Shift Supervisor. – Fairless Hills, PA

Responsible for second shift plant operations, 13 direct report employees.

February 1987 to January 1990. Cylinder Control Coord. – Valley Forge, PA

Maximized utilization of a fleet of 300,000 compressed gas cylinders.

**General Electric Co Re-Entry Systems Operation**, Philadelphia, PA.

June 1985 to January 1986. Co-op student, Procurement Expediter.

March 1984 to December 1984. Co-op student, Production Controller

December 1982 to June 1983. Co-op student, Laboratory Technician.

PROFESSIONAL  
LICENSES

Osteopathic Medicine - West Virginia 1602

Osteopathic Medicine - Pennsylvania OS-009608-L

PROFESSIONAL  
CERTIFICATION

Board Certified in Occupational Medicine (ABPM, expires 2023)

Board Certified in Occupational and Environmental Medicine (AOA, expires 2025)

Medical Review Officer (MROCC)

FAA Senior Aviation Medical Examiner Designee

FAA Employee Examiner Designee

Certified Driver Medical Examiner (FMCSA/NRCME)

NIOSH Spirometry Technician

Breath Alcohol Technician (Phoenix)

Wilderness Command Physician/Wilderness EMT (WEMSI)

## Basic Cardiac Life Support

FELLOWSHIP	American College of Occupational and Environmental Medicine (2006) American Osteopathic College of Occupational and Preventive Medicine (2011)
PROFESSIONAL LEADERSHIP ACTIVITIES	Tristate Occupational Medicine Association – President 2009-10, BOD 2006-present Monongalia County Medical Society – President 2009 American Osteopathic College of Occupational and Preventive Medicine Board of Trustees – 2010-2012, 2013-2015 Education Evaluation Committee Chair 2014-2016 ACGME Preventive Medicine RRC - Member 7/1/2016-6/30/2022
PROFESSIONAL MEMBERSHIPS	American Osteopathic Association. Monongalia County Medical Society (currently dormant) American College of Occupational and Environmental Medicine American Osteopathic College of Occupational and Preventive Medicine
TALKS GIVEN	<p>“Obesity and Pulmonary Function Testing (or What Pickwickian Syndrome is, and what it is not). WV Chronic Pulmonary Disease ECHO, May 6, 2019.</p> <p>“Black Lung Update”, Fayette County Black Lung Coalition, Scarbro, WV November 13, 2018.</p> <p>“Resurgence of Black Lung in Appalachia”. Annual Meeting of the TriState Occupational Medicine Association, Columbus, OH. October 20, 2018.</p> <p>“Occupational Health Hazards in ‘Unconventional’ Gas and Oil Production.” PA Health Check-Up Health Impacts of Unconventional Gas Development Industry from Pittsburgh to Philadelphia. Chatham University, Pittsburgh, PA. October 13, 2018.</p> <p>“Resurgence of Black Lung in Appalachia”. Annual Meeting of the American Osteopathic Association, San Diego, CA October 7, 2018.</p> <p>“Black Lung in West Virginia - 2018”, West Virginia School of Osteopathic Medicine noon lecture series, Lewisburg, WV. May 16, 2018.</p> <p>“Full” Pulmonary Function Testing in Assessing Lung Diseases, West Virginia Chronic Lung Disease (Black Lung) ECHO. April 2, 2018.</p> <p>“Black Lung – An Introduction for Medical Students”, West Virginia School of Osteopathic Medicine Rural Health Initiative, Beckley, WV. Dec 11, 2017.</p> <p>“Mine Rescuer Health Hazards and Drug Testing Update”. Tristate Occupational Medicine Association Meeting; Columbus, OH. October 14, 2017.</p> <p>“Post-Explosion Health Hazards for Mine Rescuers and Investigators”, with Anna Allen, MD, West Virginia State Black Lung Conference, Pipestem Resort WV, June 7, 2017</p> <p>“Miner Health and Safety and Drug Testing Update”, American Osteopathic College for Occupational and Preventive Medicine Mid-Year meeting, Chattanooga, TN; March 9, 2017.</p> <p>“Drug Testing Challenges – 2016”, Bay County Society for Human Resource Management’s Workers’ Compensation &amp; Occupational Healthcare Conference, Panama City, FL, October 13, 2016.</p> <p>“Return to Work and Functional Capacity Evaluations”, American Osteopathic College of Occupational and Preventive Medicine mid-year meeting, Fort Lauderdale, March 12, 2015.</p> <p>“Return to Work and Healthy Spine Habits”, WVU Spine Conference, Morgantown, WV, October 3, 2014.</p>

- “Human Health Concerns of Working with Research Animals”, Loren Hatch Memorial Lecture for the American Osteopathic College of Occupational and Preventive Medicine mid-year meeting, Tulsa, March 6, 2014.
- “Is this OSHA Recordable?”, Brent Lovejoy Memorial Lecture for the American Osteopathic College of Occupational and Preventive Medicine mid-year meeting, Phoenix, February 13, 2013.
- “Human Health Concerns from Hydraulic Fracturing”, Grand Rounds – Fairmont Clinic, Fairmont, WV. February 29, 2012.
- “Occupational Health Concerns from Hydraulic Fracturing”, 2nd Annual Conference on Health Effects of Shale Gas Extraction, Pittsburgh Graduate School of Public Health, November 18, 2011.
- “Human Health Concerns from Hydraulic Fracturing”, Tristate Occupational Medicine Assn annual meeting, Cleveland, OH. October 22, 2011.
- “Human Health Concerns from Hydraulic Fracturing”, Pennsylvania Occupational and Environmental Medical Society annual meeting, Harrisburg, PA. September 19, 2011.
- “Human Health Concerns from Hydraulic Fracturing”, Cambria-Summerset Health Council CME Conference, Seven Springs, PA. September 17, 2011.
- “Case Studies from Residency” (2 Hour Interactive session) American Osteopathic College of Occupational and Preventative Medicine mid-year meeting, Atlanta, March 2011.
- “Slurry and Tetryl and Fracking – OH MY! – New Environmental Health Concerns in WV”, WV School of Osteopathic Medicine Mid-Year CME meeting, Charleston, WV, February 2011.
- “Slurry and Tetryl and Fracking – OH MY! – New Environmental Health Concerns in WV”, Tristate Occupational Medicine Annual Session, Columbus, OH, October 2010.
- “Slurry and Tetryl and Fracking – OH MY! – New Environmental Health Concerns in WV”, American Osteopathic Association Annual Meeting, San Francisco, October 2010.
- “Finding a Needle in a Haystack – The Search for Jacob Allen in Dolly Sods, October, 2007”, Appalachian Wilderness Medicine Conference, Morgantown, WV, August, 2008.
- “Land Navigation using GPS, map, and compass”, Appalachian Wilderness Medicine Conference, Coopers Rock State Forest, August, 2008.
- “Human Health Concerns for Research Animal Workers” American Osteopathic College of Occupational and Preventative Medicine mid-year meeting, Savannah, GA, March 27, 2008.
- “Cave Rescue”, Appalachian Wilderness Medicine Conference, Morgantown, WV, August, 2007.
- “Land Navigation using GPS, map, and compass”, Appalachian Wilderness Medicine Conference, Coopers Rock State Forest, August, 2007.
- “Occupational Health with research animals”, Occupational Medicine Grand Rounds, July 2007.
- International Occupational and Environmental Medicine (2 Hours) for WVU certificate course in tropical and travel medicine, June 2007.
- “Respirator Medical Clearance”, American Osteopathic College of Occupational and Preventative Medicine annual meeting, Las Vegas, NV, October 2006
- “Wilderness EMS and Field Treatment of Hypothermia”, Appalachian Wilderness Medicine Conference, Canaan Valley, August, 2006.
- “International Occupational and Environmental Medicine” (4 Hours) for WVU certificate course in tropical and travel medicine, June 2006.

“What’s new in Spirometry”, American Osteopathic College of Occupational and Preventative Medicine, annual meeting, Orlando FL, October 2005.

“The Community Practitioner’s Role in Outbreak Response”, West Virginia University Public Health Grand Rounds, February, 2005.

“Drug Testing for the non-MRO”, Occupational Medicine Grand Rounds, August, 2004.

“Occupational Health in Chile”, West Virginia University Certificate Course in Tropical Medicine, Morgantown, WV, June 26, 2002.

“Zinc Protoporphyrin Changes Following Acute Lead Intoxication”, American Occupational Health Conference, Chicago, IL April 16, 2002.

“Wilderness Emergency Medical Services”, Marshall University Wilderness Medicine Grand Rounds, Huntington WV, February 21, 2002.

“Medical Mission to Guatemala”, West Virginia University Certificate Course in Tropical Medicine, Morgantown, WV, July 16, 2001.

“Wilderness Emergency Medical Services”, West Virginia University Department of Emergency Medicine Grand Rounds, April 20, 2000.

“Case report of gastric ulcerations after electrocution without significant external injury”; American College of Physicians - West Virginia Chapter, Lakeview Resort, Morgantown, WV, May 21, 1999.

**COURSE FACULTY** American Osteopathic College of Occupational and Preventive Medicine-Basic Course in Occupational Medicine – [Rotating series of 3 sessions, each offered every 18 months]. I provide lectures all three sessions, including Introduction to Occupational Medicine, Medical Surveillance, Hearing Conservation, Substance Abuse and Drug Testing, Biologic Hazards, Metal Toxicology, Solvent Toxicology, Introduction to Toxicology, Reproductive Hazards, Facility Walkthroughs, and ADA/FMLA/GINA.

American Osteopathic College of Occupational and Preventive Medicine – Commercial Driver Medical Examiner Course - Lead Instructor and lecturer on diabetes, hypertension, cardiovascular, respiratory, neurologic, and psychiatric diseases, vision, hearing, waivers and the SPE process.

2002 – 2018: WVU Residency program in Occupational Medicine – I provided education sessions on: Medical Surveillance, Hearing Conservation, ADA/GINA/FMLA, Biologic Hazards, Non-Conventional Gas Production, WV Environmental Health "disasters", Return to work and FCEs, Biosafety and Viral Vectors, OSHA Logs, Recordability and Reportability, Drug testing for the non-MRO, Commercial Driver Medical Examiners, Dysbarisms & Altitude, Payors in the US healthcare system, Cultural Competency in WV, coke oven worker surveillance, Benzene medical surveillance, Emergency Response for public health, Firefighter & emergency responder medical standards.

## PUBLICATIONS

Allen, AM, and **Werntz CL**, Respondents, “What are the Potential Health Effects on Mine Rescuers and Investigators After a Mine Explosion?” Journal of Occupational & Environmental Medicine, Occupational Medicine Forum: May 2017 - Volume 59(5), pp e97–e98. PMID: 28486348

Sully K, Schaefer M, Allen A, **Werntz CL 3rd**, Ma G, Sayeed Y. Musculoskeletal Ultrasound Use Among Occupational Medicine Practitioners at the American Occupational Health Conference. J Occup Environ Med. 2016 Aug;58(8):e315-7. PMID: 27501000



Alfaraj WA, McMillan B, Ducatman AM, **Werntz CL 3<sup>rd</sup>**. Tetryl exposure: forgotten hazards of antique munitions. *Ann Occup Environ Med.* 2016 Apr 8. PMID: 27066259

Sayeed Y, Marrocco A, Sully K, **Werntz CL III**, Allen A, Minardi J. Feasability and Implementation of Musculoskeletal Ultrasound training in Occupational Medicine Residency Education. *J Occup Environ Med.* 2015 Dec;57(12):1347-52. PMID: 26641833

Sayeed Y, , Minardi J, Kurdi H, **Werntz CL 3<sup>rd</sup>**. Musculoskeletal ultrasound in American Occupational Medicine residency programs: a survey of program directors. *J Occup Environ Med.* 2015 May;57(5):e55-6. PMID:25951425

Sayeed Y, Sully K, Allen A, **Werntz CL**. The Emerging Role of Musculoskeletal Ultrasound in Occupational Medicine. *Vol 56(12), Dec 2014, p e160.* PMID: 25479308

**Werntz CL**, Respondent, “Fitness for Duty Evaluations: How Should Blood Pressure Be Considered?” *Journal of Occupational and Environmental Medicine*, Vol 52(3), pp355-357. (Schwerha J, Forum Editor) PMID: 20216368

Ducatman AM, Jin C, **Werntz CL**. *Occupational Toxicology*, Chapter in *General and Applied Toxicology*, 3<sup>rd</sup> Edition, Wiley & Sons, London, Nov 2009.

**Werntz CL**, Respondent, “Workers at Height are Required to Use Fall Prevention Systems. What are the Health Risks from Being Suspended in a Harness?” *Journal of Occupational and Environmental Medicine*, Vol 50(7), pp 858-9. (Schwerha J, Forum Editor) PMID: 18617843

Conover K, ..., **Werntz CL**, ..., Chapter “Wilderness” in *Pre-Hospital Trauma Life Support*, 6<sup>th</sup> edition, August 2006. (Listed as contributor to book).

Martin CJ, **Werntz CL**, Ducatman AM “The interpretation of Zinc Protoporphyrin changes in lead intoxication: a case report and review of the literature”, *Occupational Medicine*, Vol 54, No 7, Dec, 2004. PMID: 15576877 Viewable at: <http://occmed.oupjournals.org/cgi/content/abstract/54/8/587?ijkey=41aqXOK0sOfUQ&keytype=ref>

#### AUTHORSHIP

“Fourteen Year Old Caught in Chain Hoist”, NIOSH FACE report 2001-13 Available at <http://www.cdc.gov/niosh/face/In-house/full200113.html>

#### ACADEMIC ACTIVITIES

Student Ambassador, Kirksville College of Osteopathic Medicine, 1992-96.  
President, Drexel University Amateur Radio Club, 1982 to 1985  
Assistant Chief Engineer, Radio Station WKDU, Drexel University, 1982-88.

#### COMMUNITY ACTIVITIES

Mountaineer Area Rescue Group, Inc. (Appalachian Search and Rescue Conf.)  
Search Manager. 1997-Present  
Camp Physician, Camp Mountaineer, Boy Scouts of America, summer camps 1998 - present.  
Staff Physician – BSA Summit Bechtel Reserve, Glen Jean, WV. 2014-present.  
Community Ambulance Association of Ambler, PA. Volunteer  
Driver/Attendant (EMT-MAST), 1981 to 1997.  
Eagle Scout, Boy Scouts of America.

Amateur Radio Operator, Advanced Class License.

PERSONAL  
DATA

Fluent in English & German.

Functional in Spanish.

Birthplace: Lower Merion, Montgomery County, Pennsylvania USA



## **Report of Charles L. Werntz III, D.O., MPH**

**Prepared by:**

**Charles L. Werntz III, D.O., MPH, FACOEM, FAOCOPM  
Morgantown Occupational Medicine, PLLC**

**Prepared for:**

**Kevin Thompson, Esq.  
Thompson-Barney PLLC  
2030 Kanawha Blvd East  
Charleston, WV 25311**

**Date: December 1 , 2019**

## **QUALIFICATIONS:**

My name is Charles L Werntz, D.O., MPH. My CV is attached. I am a physician, Board Certified in Preventive Medicine, specializing in Occupational and Environmental Medicine, plus previously completed residency training in Internal Medicine. I served on the faculty at West Virginia University (WVU) for 16 years. Throughout my time at WVU I provided clinical Occupational Medicine services to the community, developed and implemented medical monitoring programs for the University, and provided consultative services for employers, insurance companies, and attorneys. Medical monitoring programs I have developed or implemented included:

- Asbestos-Exposed University employees (WVU Asbestos Class Action)
- Asbestos-Exposed employees doing building renovations (EPA Criminal Division – Martinsburg, WV)
- Radiation Therapy workers working with lead (< OSHA limits for lead exposure) (WVU Hospitals & affiliated Cancer Centers)
- Community Members exposed to zinc smelter effluent and waste piles (Spelter, WV)
- Research animal workers and researchers with animal contact (WVU)
- Community members exposed to coal slurry impacted drinking water (Rawl, Mingo County, WV)
- Community members exposed to dioxins (Nitro, WV)
- Community members exposed to coal mining impacted water (Prenter, WV)
- Researchers, students, and employees working with sheep (WVU)
- Researchers working with lentiviral vector systems (WVU)
- Asbestos-exposed maintenance workers (Alderson-Broadus/Sodexo)
- Researchers working with Tuberculosis (WVU)
- Community Members exposed to coal mining impacted water (Harts, WV)
- Researchers working with Rock Mountain Spotted Fever virus (WVU)
- Researchers working with Human Papilloma Virus (WVU)
- Researchers working with wild-caught mammals (WVU)
- Community members exposed to Pb, Cd, As, Zn (Donora, PA)

## EXPOSURE REVIEW AND HEALTH HAZARDS

Children who were exposed to narcotics prior to birth suffer a condition called Neonatal Abstinence Syndrome (NAS). The clinical features and biochemical and physiologic impacts have been elegantly reviewed and explained by Drs. Anand and Howard in their reports. While there is some variability among individuals, it is clear that the effects of NAS are common to those diagnosed and treated for NAS. It is also clear that these effects continue throughout a lifetime.

Prenatal opioid exposure can cause impacts in several spheres impacting the child, some of which are overt, and others which can be occult. Many of these effects can impact the child throughout their lifetime. The goal of this program is to facilitate early detection of NAS-associated impacts so that earlier intervention can help minimize the lifelong impacts.

In a study by Desai<sup>1</sup>, they looked at the risk of a newborn developing NAS based on duration and timing of maternal opioid prescriptions. They found that there were cases of NAS found following all timings of maternal opioid prescriptions, although some timings of maternal opioid use conveyed greater risk. On this basis, I would recommend to use a definition of NAS that will allow consideration of children clinically diagnosed with NAS, based both on either test results or clinical findings, without a need to pre-screening for admitted maternal opioid use. Over the last two decades several different diagnostic codes and notations in the medical record have been used to indicate a medical diagnosis of impacts on the newborn following maternal opioids use. NAS is a fairly recent diagnostic code but for ease of reference, “NAS” is used herein to identify patients that has been medically determined to have suffered exposure to opioids in utero.

For the purposes of this report I am using the following definition of NAS:

*Children born after March 16, 2000, who were medically diagnosed with opioid-related “Neonatal Abstinence Syndrome” (“NAS”) at or near birth and whose birth mother received a prescription for opioids or opiates while pregnant.*

This recommended program in this report considers NAS from opioids as a child, diagnosed as being exposed to opioids in utero, who required treatment in the

perinatal period for NAS. “Treatment” would include opioid replacement therapy of the newborn, plus other treatments such as intentional changes in stimulus of the newborn to reduce the effects of NAS. In the article by Ernst<sup>2</sup>, they report “Many exposed infants can be treated with non-pharmacological methods, such as limited visitors, low lighting, swaddling, ear muffs, and cuddlers, without the need for pharmacological treatment.” All of these would be considered treatment.

The medical literature identifies several other maternal medication uses/exposures that can cause abstinence symptoms in newborns<sup>3</sup>. The recommendations in this report are intended to apply only to children where the in-utero exposure included opioids. Non-opioid withdrawal syndromes are not addressed in this report.

### SCOPE OF NAS EFFECTS

NAS is classically thought of as a medical condition that impacts newborns immediately after birth. This typically includes the effort to replace and then wean newborns off opioids while medically managing the physiologic impacts of both the narcotics and their withdrawal. These efforts can require treatment from a matter of weeks to months or even longer.

However, it is clear that the effects of NAS can be far more serious and continue well beyond the weaning the child off opioids.

Prenatal opiate exposure is associated with several congenital defects<sup>4,5</sup>. Some of these are pervasive and can be detected shortly after birth, but others can only be diagnosed later in childhood, sometimes only via testing. Examples of these impacts are outlined in table 5 of Dr. Howard’s report.

There are well-established protocols for the assessment and management of these infants, which should be followed. One important concept is that treatment of NAS in infants often requires giving them slowly decreasing doses of narcotics for a period of time. While medically necessary, this prolongs their exposure time, and thus prolongs the “time under the curve” of exposure to opioids for their developing organs. In his report, Dr. Howard outlines these effects in the section of his affidavit titled CNS and apoptosis, focusing on the impacts on the developing brain.

Given the clear evidence of persistent effects of NAS impacting school performance, a primary goal of this program is to give these children the best opportunity for success in school and later in life. Dr. Anand discusses the educational and social impacts of NAS in sections 7, 8, and 9 of his report. There is copious literature (reviewed below) that discuss the breadth and importance of the educational impacts of NAS.

#### PHYSIOLOGICAL IMPACT OF PERINATAL NARCOTIC EXPOSURE

The development of the human brain before and after birth is complex, and multifactorial. There are general themes about the timing of organ development, but the development of the pathways and mechanisms necessary for learning, understanding, decision making, and behavior control are not completely understood.

In his report, Dr. Anand notes the various physiologic processes of the development of the infant, both pre- and post-delivery, that are impacted by exposure to opioids. There is a growing body of evidence that there are lifelong impacts from the exposure to narcotics during the time of organogenesis, especially the development and maturation of the brain.

The long-term consequences of NAS for each child is multifactorial, depending on individual differences expected between humans that are difficult to determine with specificity but a medical monitoring program is necessary for all of NAS victims they all face common risks of latent disease that can be mitigated and abated through medical monitoring.

Because of these children face a common risk, the best approach is to establish a program where each child is periodically assessed and provided access to the specific resources and treatment(s) that they need to overcome the long-term impacts of NAS.

#### LITERATURE REVIEW

In his report, Dr. Howard provides an overview of the toxicology of exposure to opiates in the neonate. Please refer to this document for a review of the biochemical description of the impacts of prenatal opiate exposure on the child.

As outlined in Dr. Howard's report, laboratory scientists have identified several impacts of opioids on the developing brain. Epidemiologists have studied cohorts of exposed children and identified impacts in educational success specifically impacting NAS survivors. This literature<sup>6,7,8,9,10</sup> is based upon following cohorts of NAS children over time and comparing the effects/outcomes with those seen in socioeconomically similar children who were not NAS survivors. This is not new information, as there were several studies<sup>11</sup> during the 1990s looking at this issue.

There is a suggestion in the literature that exposed children can exhibit impacts of maternal opioid use, even if the baby did not develop clinical NAS<sup>6</sup>. This study identified opioids in maternal drug testing, then monitored children whose mothers had positive and negative drug tests over time. This study found impacts in the children, including those who did not manifest acute symptoms of NAS. The observed effects in this group include increased prevalence of behavioral or emotional disorders, developmental delay, speech disorder, and strabismus. These findings are similar to those found in survivors of NAS. I fully endorse the conclusion of this study: "Awareness of the increased risk for certain developmental delays and medical conditions is critical to early intervention and treatment supporting improved outcomes."

#### LIFELONG IMPACTS OF MATERNAL OPIOID USE

Documented lifelong impacts includes:

- Delayed achievement of early developmental milestones<sup>12,13</sup>
- Impacts on high school academic performance below that accounted for by socioeconomic status<sup>14</sup>
- Increased rates of hospitalization<sup>15</sup>
- Delayed/impaired Speech
- Impaired Hearing (reported frequently)
- Strabismus ("crossed" eyes)<sup>13</sup>
- Smaller brain size on imaging (shows permanent physiologic impact)

Additionally, there are other effects mentioned repeatedly in review and summary articles, but for which I did not locate primary literature. These include increased prevalence of Attention Deficit diseases (ADHD & ADD), increased risk of addiction as a teen, and increased rates of incarceration. Many studies discuss “behavioral” problems, which may be a catch-all for these outcomes. Other than annual assessment of drug use risk (and referrals for further interventions if increased risk is identified), these conditions were not considered in the development of this program. If evidence becomes available supporting these (or any other) conditions in NAS survivors, it would be appropriate to update the program to include appropriate screening and interventions for those additional conditions. An important part of this medical monitoring program must include medical surveillance for those individuals who are part of the program’s registry.

The authors of the study of High School academic performance<sup>14</sup> opine that their study “adds to medical knowledge”:

*Australian children with NAS perform poorly at school from grade 3, and results deteriorate even more by high school, suggesting that children with NAS must be supported beyond withdrawal to minimize the risk of school failure and its consequences.*

The recent trends in the increased prevalence of NAS limits the long-term data on exposed cohort. Pre-term babies have been long known to have impacts that, while differing in the details, are generally parallel to those in NAS. On this basis, it should be useful to look at how specific interventions are used assist preterm infants. One clear lesson from this literature is that when developmental impacts are identified and treated earlier, the child will do better over their lifetime<sup>17</sup>.

Because of the uncertainty of the specific impacts on an individual child, the best approach would be to monitor each impacted child via appropriate periodic testing, and ensure they have access to needed interventions as early as possible for identified abnormalities.

There is clear impairment in school performance, documented both in primary school<sup>7</sup> and then more profoundly in high school<sup>14</sup>, but also identified in pre-school children. Because of the impacts seen across the educational spectrum, a program



that assesses children annually, focusing on age-specific impacts and potential interventions, is recommended.

Additionally, parenting a NAS survivor is difficult, with an increased risk of hospitalization of the child<sup>15</sup>, some of which seem related to parenting difficulties. An educational program aimed at increasing the understanding of NAS in parents and other caregivers is recommended, including access (or referral) to resources for both the caregiver and the child.

This program is intended to yield the earliest possible identification of roadblocks the child is experiencing, allowing the earliest possible initiation of treatment to aid the child in overcoming the difficulty, and providing them the best opportunity for success in society as an adult.

#### GOALS OF A MEDICAL MONITORING PROGRAM

The nature of the exposure(s) and the known outcomes from prenatal opiate exposure drives the structure of the program. Goals of the program include biologic monitoring of known exposures, testing for the development of known diseases/effects, monitoring for development of disease(s) in the exposed population so that early interventions can be undertaken.

The first step in a monitoring program is to identify NAS survivors and collect their information in a registry. This will allow for the program to reach out to impacted families at the appropriate times and to understand the geographic distribution of survivors to coordinate the delivery of services to the impacted population. The registry may also support ongoing data analysis to support identifying problems, assessing the effectiveness of interventions, and adjusting the program to maximize benefit to those affected.

There are several variables that make the design of this program complex. There is considerable variability between individuals regarding the timing of their prenatal exposures, their individual tolerance for specific exposures, and the duration and effectiveness of treatment both in the hospital and after discharge. Variability between humans means that even with similar exposures there can be different outcomes.

The goal of this medical monitoring programs is to do routine focused assessments to identify the individual NAS survivors to identify those who are actually suffering a specific impact so that they can receive rapid referral for appropriate interventions. Interventions will need to be tailored to the specific deficit(s) in a given child, and could include specific treatments, education for the child or caregiver, assistance with accessing existing school-based services, or (when there is an unconfirmed suspicion of a deficit) providing additional screenings.

In the past, medical monitoring programs have also been designed to monitor and surveil for actual impacts in scenarios where the human health effect of an exposure were not entirely clear, such as a the PFOA/PFOS program around in the Little Hocking, OH/Parkersburg, WV and adjacent areas of Ohio and West Virginia. That program studied the exposed communities then used a panel of scientists to look for effects that were, and were not, found in the population. The results were then published in the scientific literature. In environmental exposure settings, the EPA has set forth criteria when medical surveillance is recommended under CERCLA<sup>16</sup>. Although this exposure is not covered in CERCLA, the exposures scenario in NAS is an analogous contamination of the environment of the fetus and would likely meet the criteria for establishment of a medical monitoring program if this scenario was covered under CERCLA. These criteria also provide for medical surveillance to determine as yet undiscovered associations between exposures and negative health outcomes.

Medical monitoring of exposed populations has been used for decades to track people with workplace exposures. Examples of common workplace medical monitoring programs include hearing conservation where noise-exposed workers get annual hearing tests, and if they develop hearing changes then they are further protected from noise exposure, and if their hearing loss is severe, the worker may be referred for hearing aids or even sign language classes in an effort to limit disability. Coal miners are offered chest x-rays every few years, and those developing evidence of black lung are given the opportunity to transfer to a job with lower dust exposure, with the goal of preventing progression of the black lung. A community-based example is screening children for lead poisoning in communities with lead contaminated drinking water, hosting battery manufacturers

or smelters, or with older homes with leaded paint. In the past I have crafted medical monitoring programs for a variety of scenarios listed under qualifications.

Monitoring is especially important for exposures involving children, as these can yield lifelong impacts on the children. Programs with special monitoring for children I have been involved with included Smelter impacts in Spelter WV, coal slurry injection impacted drinking water in Rawl WV, and coal mining impacted water in Seth/Prenter WV and Harts WV, and lead contamination of the community around Donora, PA.

Medical monitoring is not meant to replace usual medical care and programs should include only assessments and testing that are not routinely recommended for a similar person. Care must be used in selecting minimally invasive assessments that are acceptable to the community to promote participation.

In this case there are two goals for a medical monitoring program, the first, and most important, being to detect known long-term effects to enable early treatment, and the second is to collect data about the long-term impacts of NAS.

NOTE: There are current protocols for the assessment and treatment of narcotic-exposed children through their first year of life. It is recommended that these recommendations be followed. The first year of life will not be addressed in this recommendation.

There is no literature specifically focusing on interventions for NAS survivors. However, there is copious literature on interventions for other similar perinatal impacts, specifically prematurity. A recent Cochrane Review identified benefits from early interventions<sup>17</sup> in premature infants, another condition causing developmental impacts.

## PROPOSED MEDICAL MONITORING AND INTERVENTION PROGRAM

The following specific program is recommended to assess and treat the lifelong effects of prenatal opioid exposure, including NAS, with the goal of giving the exposed children the best opportunity to live a normal life.

It is recommended that starting at 1 year of age a 7-part program be established and made available to impacted children, including the following (expanded below):

1. Development and delivery of an educational program for parents and caregivers focusing on potential outcomes and benefits of interventions
2. Annual Pediatrician Assessment, including specific topics
3. Specialist assessment for deficits known to be associated with NAS
4. Annual Social Worker Assessment through starting school
5. Specialty medical evaluations at appropriate intervals
6. Vocational Rehabilitation assessment and assistance
7. Data collection, analysis, and publication on the long-term effects seen in these children

#### 1. EDUCATIONAL COMPONENT FOR CARETAKERS

Children who survived NAS are at risk of developing a broad range of developmental hazards, and often live with their parents in difficult circumstances<sup>18</sup>, some of which are obvious while others are more subtle. The goal of this educational program, in more-or-less annual installments throughout childhood to provide information on the effects of NAS, effective strategies to address specific behaviors/manifestations, and anticipatory guidance to parents and caretakers of NAS survivors. The goal of this effort is to make caretakers more aware of the NAS-related special challenges these children may present, responses and interventions that are helpful, additional support that is available, and how/when to access additional assessments and treatment. This education program must include resources for participants with limited literacy, and no written materials should ever be above the 8<sup>th</sup> grade reading level.

#### 2. ANNUAL ASSESSMENT - PEDIATRICIAN

Annual assessment with a pediatrician or other physician familiar with NAS through age 10. This should include:

- Growth and nutritional Assessment
- Assessment for strabismus (the cover/uncover test)
- Assessment of substance abuse risk and participation, with referral to treatment for any identified substance use

- Transportation to and from this assessment should be provided upon request.

### 3. EDUCATIONAL READINESS ASSESSMENT

From age 1 through starting school, the child (and their family) shall have an Annual Family Support Assessment performed by a Social Worker or other child welfare specialist. The initial screen could be done by the pediatrician, with immediate access to a social worker for further assessment for any “yellow flags”.

### 4. ADDITIONAL (SPECIALIST) ASSESSMENTS

- Age - about 12 months - Neurodevelopmental Assessment. This screening could be performed by local “birth-to-three” program personnel.
- Age - about 12 months – echocardiogram to assess for Atrial Septal Defect (if not done previously)
- Age 2 – Audiology Assessment
- Age 3 - Ophthalmologic assessment for strabismus (per literature, limited effectiveness at younger ages<sup>19</sup>)
- Age 5-6 - Psychosocial Assessment (or at any age if symptomatic) Specifically looking for symptoms of ADHD and other developmental problems that could interfere with education.
- Age 5-7 years old - Ophthalmologic Re-assessment for strabismus and need for vision correction<sup>19</sup>.

NOTE: Any child with a potential NAS-related abnormality identified during either the pediatrician or social worker annual assessment or in another setting (for example during an illness visit or at school), should have access to the indicated specialty assessment and treatment.

### 5. ADDICTION/SOCIAL RISK ASSESSMENT

From ages 10-18, each participant shall be screened annually by a practitioner specializing in adolescent addiction and behavioral risk. The goal of this assessment is to assess overall success of the child, including home support, risk for opiate use/abuse. Any participant deemed to be at increased risk would be referred to a specialist in adolescent addiction for

assessment and potential treatment. This may include drug and alcohol testing at the discretion of the practitioner.

#### 6. VOCATIONAL ASSESSMENT AND RECOMMENDATIONS

At ages 12, 15, and for 1 year following high school graduation. This assessment is intended to assist impacted children with career choice and preparation. The poor academic performance seen in studies may make post-secondary education difficult for many of these children. Early assessment will aid those children unlikely to enter college in finding a career path and preparing for a career while they are in high school to provide impacted children the best opportunity for a successful transition to adult life.

#### 7. DATA COLLECTION, ANALYSIS, AND PUBLICATION

As mentioned several times, there is limited information on the long-term effects of NAS, and effectiveness of specific interventions. The final aspect of this program would be a funded arrangement with an academic or public health organization to collect, curate, analyze, and publish the results of the assessments, interventions, and outcomes of NAS survivors. This epidemiologic component confers a medical benefit to the population.

#### OVERALL PROGRAM RECOMMENDATIONS:

- Participation in the entire program is voluntary, and any participant can choose to participate or discontinue participation at any time. Note that enrollment in the Registry may occur without action by the child or their caregiver, but any further participation would be voluntary.
- To facilitate participation in this program, it is recommended that as many barriers to participation be addressed as possible, including:
  - a. Providing funding for transportation for assessments
  - b. Providing token compensation to participants
  - c. Facilitating access by offering home visits (or at a location familiar and convenient to the patient) whenever possible to both facilitate participation and to allow the assessment to consider living situation.

- Delivery of this program on a nationwide basis will require a broad network of providers. To the extent possible, this network should be formed using providers familiar with the long-term impacts and treatment for NAS.
- That any participant who fails to participate in evaluations or treatment beyond the initial screening will receive a letter communicating the recommendations for the services that were missed and a mechanism to access those services.
- In all cases, the evaluating physician/provider shall have the freedom to repeat evaluations or order confirmatory testing if there are inconclusive results or evidence of a lab error or some other reason to question the result.
- If a patient has had any of the recommended tests within the past 6 months, and the written results these can be obtained, those tests will not be repeated, and the patient-provided results used for the screening program.
- Should a non-NAS-related condition be identified, the patient will be referred to their PCP for evaluation and care.
- A patient with an abnormal finding related to the exposures will be referred to the appropriate specialist with each screening cycle.
- That a central repository of the screening, referrals, and outcomes data will be maintained, and depersonalized data made available for epidemiological evaluations. This would ideally be a function of the registry, if established.
- The screening program described here is based upon the best available medical knowledge in 2019. It is certain that in the future new technology or better understandings of the long-term effects of NAS may require updating of this program. This could be based upon changes in medical knowledge, improvements in technology to detect diseases associated with these exposures, or additional conditions of concern that are identified by the epidemiologist. This protocol should be reviewed periodically by the supervising physician or a committee appointed for that purpose to ensure that the screenings and follow-up described here remain consistent with best medical practice.

This report is based upon the information available at the time it was prepared. With the unfortunate increase in NAS cases, the scientific understanding of NAS and outcomes in NAS survivors continues to evolve. I reserve the right to update this report to reflect changes in science and medicine as necessary.





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Deposition/Testimony History of Charles L. Wernitz III, D.O.				Print Date	12/1/2019		
DATE	Entered Matter Via	Vendor	Case/Claimant Name	CLAIM NO / Nature	Activity	Trial Venue	Case Number
6/4/03		Pullin	Green	410-046287	Depo		
6/26/03	WV WCC IME	WV WCC	Taylor	?	Depo		
10/6/03	WC WCC IME	WV WCC	Jeffries	2002015806-INJ	Depo		
6/14/04	US DOJ	US EPA Prosecutors	US v. Mauck/Rind	DOJ File 198-83-00393	Testimony	US District Ct - Martinsburg	
7/12/04	WV WCC IME	WV WCC	Hercules	2003050641	Depo		
9/9/04	WV WCC IME	WV WCC	Grimes	2003037318	Depo		
11/16/04	WV WCC IME	WV WCC	McFadden	940039531	Depo		
1/3/05	US DOJ	DOJ/ENRD	US v. Mauck & Rind	DOJ File 198-83-00393	Trial	US District Ct - Martinsburg	
2/18/05	WV WCC IME	WV WCC	Smith	200302822	Depo		
3/1/05	WV WCC IME	WV WCC	Baker	2003055479	Depo		
7/18/05		Yablonski, Costello & Leckie	Schultz	Railroad Injury	Depo		
4/22/05	Evidence Management	Evidence Management	Rawl, WV	Water	Depo	Mingo Co, WV	
10/11-12/06	Levin, Papantonio	Levin, Papantonio	Drummond v Dupont	Expert Report	Depo	Harrison Co, WV	
11/2/06	Treatment Patient	McNeer, Higland, Roberts	Davis (Higgins)	Car Wreck	Depo	Harrison Co, WV	
1/4/07	Levin, Papantonio	Levin, Papantonio	Drummond v Dupont	Expert Report	Depo	Harrison Co, WV	
4/11/07	Levin, Papantonio	Levin, Papantonio	Perrine (Spelter, WV)	Expert Report	Depo	Harrison Co, WV	
10/2/07	Levin, Papantonio	Levin, Papantonio	Perrine (Spelter, WV)	Expert Testimony	Testimony	Harrison Co, WV	
1/15/08	Levin, Papantonio	Levin, Papantonio	Perrine (Spelter, WV)	Expert Testimony	Testimony	Harrison Co, WV	
4/10-11/2008	Thompson-Barney	Jackson Kelly	Rawl, WV	Expert Reports	Depo	Mingo Co, WV	
4/28/08	Thompson-Barney	Jackson Kelly	Rawl, WV	Expert Reports	Depo	Mingo Co, WV	
5/2/08	Thompson-Barney	Jackson Kelly	Rawl, WV	Expert Reports	Depo	Mingo Co, WV	
May 2008	Thompson-Barney	Jackson Kelly	Rawl, WV	Expert Reports	Depo	Mingo Co, WV	
6/30/08	Thompson-Barney	Thompson Barney	Jones v Concord Coll	Atty IME Report	Depo		
11/17/08	Thompson-Barney	Jackson Kelly	Rawl, WV	Expert Reports	Depo	Mingo Co, WV	
1/15/09	Thompson-Barney	Jackson Kelly	Rawl, WV	Expert Reports	Depo	Mingo Co, WV	
1/29/09	Spine Center Eval	Cipriani & Werner	Cheryl Swihart	PA WC Treating	Depo		
7/13/09	Thompson-Barney	Jackson Kelly	Chauncey, WV	Expert Reports	Depo	Logan Co, WV	
7/15/09	Thompson-Barney	Jackson Kelly	Chauncey, WV	Expert Reports	Depo	Logan Co, WV	
11/17/09	Treating Physician	Neil J. Marcus, Esq	Anthony Burnsworth	PA WC Treating	Depo		
12/7/09	Barton, Kilgore, & Lazenby	Barton, Kilgore, & Lazenby	Lusk, et al	Expert Report	Depo		
2/8/10	Examining Physician	Bailey & Wyatt, PLLC	Elizabeth Julio	Examining Physician	Depo		
5/26/10	Caldwell Practice	Caldwell Practice	Nitro, WV	Expert Report	Depo	Kanawha Co, WV	
7/19/10	Examining Physician	Bailey & Wyatt, PLLC	Elizabeth Julio	Examining Physician	Video Testimony	Brooke Co, WV	
1/14/11	Thompson-Barney	Jackson Kelly	George Keller	Treating Physician	Phone Depo		
1/19/11	Thompson-Barney	Jackson Kelly	Marsh Fork School	Expert Report	Depo	Raleigh Co, WV	
2/24/11	Thompson-Barney	Jackson Kelly	Marsh Fork School	Expert Report	Depo	Raleigh Co, WV	
3/17/11	Thompson-Barney	Thompson-Barney	Marsh Fork School	Expert Testimony	Daubert Hearing	Raleigh Co, WV	
3/18/11	Thompson-Barney	Thompson Barney	Marsh Fork School	Expert Testimony	Testimony	Raleigh Co, WV	
5/4/11	Levin, Papantonio	Levin, Papantonio	Callie Savage	Expert - Med Mal	Depo	Osceola Co, FL	
6/14/11	Thompson-Barney	Thompson Barney/JK Split	Rawl, WV	Expert Reports	Depo	Mingo Co, WV	
12/15/11	IME Physician	Jackson Kelly	Danielle Pettie	IME Report	Depo		
12/29/11	Treating Physician	Cipriani & Werner	Sal Bombardiere	Treating Physician	Depo	US Dist Ct N. WV (Wheeling)	
2/23/12	Smith Stag	Spilman Thomas	Hagy Family	Expert Reports	Depo		
3/1/12	Smith Stag	Spilman Thomas	Hagy Family	Expert Reports	Depo		
3/12/12	Sutter Law Firm	Jackson Kelly	Seth/Prenter	Examining Physician	Depo	Boone Co, WV	
3/19/12	Sutter Law Firm	Jackson Kelly	Seth/Prenter	Examining Physician	Depo	Boone Co, WV	
4/16/12	Sutter Law Firm	Jackson Kelly	Seth/Prenter	Expert Reports	Depo	Boone Co, WV	
4/26/12	Sutter Law Firm	Jackson Kelly	Seth/Prenter	Expert Reports	Depo	Boone Co, WV	
5/7/12	Sutter Law Firm	Jackson Kelly	Seth/Prenter	Expert Reports	Depo	Boone Co, WV	

Deposition/Testimony History of Charles L. Werntz III, D.O.				Print Date	12/1/2019			
DATE	Entered Matter Via	Vendor	Case/Claimant Name	CLAIM NO / Nature	Activity	Trial Venue	Case Number	
5/23/12	Treating Physician	Blank Rome	Sal Bombardiere	Treating Physician	Depo	US Dist Ct N. WV (Wheeling)		
7/11/12	Levin Papantonio	Levin Papantonio	Callie Savage	Expert Report	Trial Testimony	Escambia Co, FL		
9/18/12	Jackson Kelly	US DOL	David Thomas	Black Lung Exam	Depo	Federal Black Lung		
11/??/2012	Napoli Bern		Sal Bombardiere	Expert Report	Depo	US Dist Ct N. WV (Wheeling)		
3/4/13	US DOL Black Lung Exam	Jackson Kelly	Delmar Hagedorn	Examining Physician	Depo	Federal Black Lung		
3/4/13	Napoli Bern	Napoli Bern	Sal Bombardiere	Expert Physician	Trial Testimony	US Dist Ct N. WV (Wheeling)		
10/9/13	Mark McMillan		McGhee	Expert Physician	Depo			
9/3/14	Evaluating Physician	Steptoe & Johnson	Tetryl (Isaacs, Morris)	Examining Physician	Depo			
10/15/14	Treating Physician	Bowles Rice	Terry Henry	Treating Physician	Depo			
8/17/15	Record Review	Bland & Bland	Edna Brown	Records Review	Depo	Kanawha Co, WV	14-C-427	
10/21/16	Reed Smith	Spilman, Thomas & Battle	Francis Ice	Expert Reports	Depo	Harrison Co Circuit, WV		
2/27/17	Schrader, Byrd, & Companion	Schrader, Byrd, & Companion	Thomas Standiford	Expert Reports	Evidentiary Depo	Wetzel Co Circuit, WV	15-C-12	
6/12/17	Toriseva Law	Schrader, Byrd, & Companion	Gary Beagle	Examining Physician	Depo	Wetzel Co Circuit, WV	15-C-41	
4/17/18	Hartley Law Group	Bailey & Wyatt, PLLC	Dora Carbajal-de-Vences	Examining Physician	Depo	Berkeley Co, WV	17-C-98	
10/29/18	US DOL Black Lung Exam	Jackson Kelly	Jackie Easter	Examining Physician	Depo	Federal Black Lung		
12/20/18	Thompson-Barney	Bonnet Fairbourn Friedman & Balint PC	Arkema Chemicals	Expert Reports	Depo	Federal Court - Texas		
12/31/18	Angotti & Straface	Pullin, Fowler, Flannigan, et al	Dominic Mutillo	Treating Physician	Depo	Monongalia Co Circuit WV	16-C-197	
11/4/19	US DOL Black Lung Exam	US Department of Labor	Daniel Baker	Examining Physician	Depo	US DOL ALJ	2019-BLA-05517	